

EXHIBIT A

COPY

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FILED/ENDORSED

Clerk of the Superior Court

MAR 25 2022

By **D. CIMMINO**
DEPUTY CLERK

ASSIGNED TO
JUDGE STEPHEN GIZZI
FOR ALL PURPOSES

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SOLANO

MARGURITE PARIANI, on her own behalf and
on behalf of her minor child E.P.,

Plaintiff,

v.

MEAD JOHNSON & COMPANY, LLC,
MEAD JOHNSON NUTRITION COMPANY,
ABBOTT LABORATORIES, NORTHBAY
HEALTHCARE GROUP, D/B/A NORTHBAY

Case No. FC057968
FCM179181

**COMPLAINT FOR DAMAGES AND
DEMAND FOR JURY TRIAL**

(1) Strict products liability for design defect
(2) Strict products liability for failure to warn
(3) Negligence
(4) Intentional misrepresentation
(5) Negligent misrepresentation
(6) Negligent failure to warn

BY FAX

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Defendants.

Plaintiff brings this Complaint and Demand for Jury Trial (the “Complaint”) against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories, (collectively, “the Defendant Manufacturers”), and NorthBay Healthcare Group d/b/a NorthBay Medical Center (“NorthBay”) (together, “Defendants”). Plaintiff alleges the following upon personal knowledge as to Plaintiff’s own acts and experiences and upon information and belief, including investigation conducted by Plaintiff’s attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by the premature infant E.P. who was given the Defendant Manufacturers’ cow’s milk-based infant feeding products at NorthBay Medical Center. NorthBay acquired and supplied the Defendant Manufacturers’ products to E.P. and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused E.P. to develop necrotizing enterocolitis (“NEC”), a life-altering and potentially deadly disease that largely affects premature babies who are given cow’s milk-based feeding products. As a result, E.P. was seriously injured, resulting in long term health effects and accompanying harm to her parent, Plaintiff Margurite Pariani.

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of E.P.’s consumption of the Defendant Manufacturers’ unreasonably dangerous cow’s milk-based infant feeding products, which were acquired and supplied without adequate warning to E.P. by NorthBay Medical Center, a healthcare facility owned and operated by Defendant NorthBay Healthcare Group.

II. PARTIES

3. Plaintiff Margurite Pariani is a natural person and a resident of California. Ms. Pariani is the mother of E.P., a minor.

1 4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of
2 the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson &
3 Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its
4 citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson
5 Nutrition Company and Mead Johnson & Company, LLC, (together, “Mead”) are manufacturers of
6 cow’s milk-based infant feeding products and market many of these products under the “Enfamil”
7 brand name.

8 5. Defendant Abbott Laboratories (“Abbott”) is a corporation, incorporated under the laws of
9 the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow’s
10 milk-based infant feeding products and markets many of its products under the “Similac” brand name.

11 6. Defendant NorthBay Healthcare Group is a corporation, incorporated under the laws of the
12 State of California. Its principal place of business is in California. It owns and manages NorthBay
13 Medical Center, located in Fairfield, California.

14 **III. JURISDICTION AND VENUE**

15 7. This Court has jurisdiction in this matter pursuant to California Code of Civil Procedure
16 § 410.10. Defendants conduct authorized business in the State of California. They have sufficient
17 minimum contacts with and purposefully avail themselves of the markets of this State. This suit arises
18 out of Defendants’ forum-related activities, such that the Superior Court’s exercise of jurisdiction
19 would be consistent with traditional notions of fair play and substantial justice.

20 8. Venue is proper pursuant to California Code of Civil Procedure §§ 395 and 395.5 because the
21 unlawful acts and activities giving rise to this action occurred in Solano County.

22 9. This action is an unlimited civil case because the amount of damages requested exceeds
23 \$25,000 and because none of the Plaintiff’s causes of action meet the criteria for limited civil cases
24 in the California Code of Civil Procedure.

25 **IV. FACTUAL ALLEGATIONS**

26 ***E.P.’s NEC Diagnosis***

27 10. E.P. was born prematurely at NorthBay Medical Center in Fairfield, California on February
28 2, 2005.

1 11. E.P. was fed Similac and/or Enfamil cow's milk-based products by NorthBay's staff from
2 shortly after her birth.

3 12. Shortly after E.P. first ingested the Defendant Manufacturers' products, she developed NEC.

4 13. E.P. has continued to suffer long term health issues.

5 ***Cow's Milk-Based Feeding Products Are Known to Cause NEC***

6 14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder
7 affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine,
8 causing portions of the intestine to become inflamed and often to die. Once NEC develops, the
9 condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30
10 percent of NEC-diagnosed infants die from the disease.

11 15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their
12 underdeveloped digestive systems. Extensive scientific research, including numerous randomized
13 controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and
14 low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term
15 health problems, and death.

16 16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to
17 ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-
18 fed babies and three times more common in babies who received a combination of formula and breast
19 milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those
20 only fed cow's milk formula than in those fed breast milk.

21 17. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-
22 based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment),
23 compared to preterm babies fed a diet that included some cow's milk-based products.

24 18. Yet another study that analyzed the data from a 12-center randomized trial concluded that
25 fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of
26 NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast
27 milk-based fortifier.

1 19. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding,
2 warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of
3 necrotizing enterocolitis." The report also states that premature infants who are not breastfed are
4 138% more likely to develop NEC.

5 20. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to
6 the optimal physical, mental, and social health and well-being for all infants, children, adolescents,
7 and young adults," has advised that all premature infants should be fed either their mother's milk or,
8 if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based
9 on the "potent benefits of human milk," including "lower rates of . . . NEC."

10 21. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants
11 fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-
12 birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

13 22. Another study conducted a randomized comparison of extremely preterm infants who were
14 given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing
15 variable amounts of cow's milk-based products. The babies given exclusively breast milk products
16 suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

17 ***Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist***

18 23. A range of options are available that allow preterm and low-birth-weight infants to be fed
19 exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an
20 established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover,
21 hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

22 24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition
23 necessary to support premature and low-birth-weight infants without the elevated risk of NEC
24 associated with cow's milk-based products. For example, in a study analyzing preterm infants who
25 were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded
26 standard growth targets and met length and head-circumference growth targets, demonstrating that
27 infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast
28 milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide

1 the additional nutritional supplements necessary for adequate growth while receiving the protective
2 benefits of a breast milk diet.

3 25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also
4 displace the breast milk they could otherwise receive. This displacement only increases infants'
5 vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a
6 study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-
7 based diet is associated with significant benefits for extremely premature infants and that it produced
8 no feeding-related adverse outcomes.

9 26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for
10 preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while
11 creating a significantly lower risk of NEC.

12 27. At the time E.P. was fed the Defendant Manufacturers' products, the science clearly
13 demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a
14 baby will develop NEC, leading to severe injury and often death.

15 28. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products
16 present a dire threat to the health and development of preterm infants, the Defendant Manufacturers
17 have made no changes to their products or the products' packaging, guidelines, instructions, or
18 warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition,
19 they incentivize hospitals that know the risks to use their products by providing them to the hospital
20 for free or at a significant discount, in order that vulnerable infants and their families will become
21 accustomed to using their products before discharge.

22 ***The Defendant Manufacturers' False And Misleading Marketing***
23 ***Regarding Cow's Milk-Based Infant Products***

24 29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically
25 endorsed and nutritionally equivalent alternatives to breast milk, including prior to E.P.'s birth.

26 30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants
27 while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk
28 formulas and fortifiers are necessary for the growth and development of their vulnerable children.

1 Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's
2 supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their
3 promotional websites, reference the science showing how significantly their products increase the
4 risk of NEC.

5 31. Numerous studies have shown the detrimental impact of formula advertising on the rates of
6 initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-
7 breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

8 32. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along
9 with other formula manufacturers, are willing to spend massive sums to disseminate their message,
10 with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing
11 and promotion in 2014 alone.

12 33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health
13 Assembly—the decision-making body of the World Health Organization—developed the
14 International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies
15 to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing
16 partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also
17 forbade advertising or other forms of promotion of formula to the general public as well as providing
18 sample products to mothers or members of their families.

19 34. While Abbott and Mead acknowledge the Code on their websites and claim to support the
20 effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service.
21 Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—
22 that the nutrition they are supplying to their child will not provide the best chance of survival—while
23 wholly failing to warn that their products come with a significantly increased risk of NEC.

24 35. For example, Abbott's website, on a page titled "Infant Formula Marketing," states: "We
25 agree with the World Health Organization that breastfeeding provides the best nutrition for babies,
26 and we support its goal to increase breastfeeding. We also recognize that for infants who aren't
27 breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative
28

1 to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as
2 human milk-based formula.

3 36. Abbott markets and sells multiple products specifically targeting preterm and low-birth-
4 weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers,
5 Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac
6 Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to
7 assist underdeveloped babies in reaching their growth targets. For example, on the since-edited
8 webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9
9 months in the womb, so her body is working hard to catch up. During her first full year, feed her
10 Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help
11 support her development." Yet, no mention was made of the accompanying significantly increased
12 risk of NEC. At some point, the website was edited to remove this statement. However, upon
13 information and belief, the statement remained on the website until at least December 2020.

14 37. Mead markets and sells multiple products specifically targeting premature infants, including
15 Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein,
16 Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with
17 Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and
18 Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead
19 emphasizes the purported similarities between its formula and breast milk, while failing to include
20 any information about the nutritional deficits and dangers that accompany formula use. For example,
21 the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas
22 during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and
23 noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty
24 acids found naturally in breast milk) to support brain and eye development."

25 38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is
26 entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of
27 the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in
28 the advertisement, including in such statements as "for decades human milk has inspired the

1 advancements in Enfamil formulas and now through extensive global research, we are taking an even
2 closer look at human milk” and “only Enfamil NeuroPro has a fat blend of MFGM and DHA
3 previously found only in breast milk.” The webpage for the product has made similar manipulative
4 claims, stating “Enfamil is backed by decades of breast milk research and multiple clinical studies”
5 and it claims that “to create our best formulas, we collaborated on some of the most extensive breast
6 milk studies to date[.]”

7 39. Formula manufacturers have long used their relationships with hospitals and the discharge
8 process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost
9 formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and
10 even entire gift baskets to parents before their infants’ discharge from the NICU or hospital.

11 40. Through this early targeting, the Defendant Manufacturers create brand loyalty under the
12 guise of a “medical blessing,” in hopes that new parents continue to use formula after they leave the
13 hospital, resulting in increased expense for parents, significantly increased risk for babies, and
14 increased profit for the Defendant Manufacturers. The Defendant Manufacturers’ giveaways and gift
15 baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by
16 their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

17 41. Further, when the Defendant Manufacturers recognized a shift in the medical community
18 towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called
19 “Similac Human Milk Fortifier,” and Mead developed “Enfamil Human Milk Fortifier.” These
20 names are misleading in that they suggest that the products are derived from breast milk, when, in
21 fact, they are cow’s milk-based products. One study, for example, found that only 8.8 percent of
22 parents surveyed in the NICU interpreted “human milk fortifier” as potentially meaning a cow’s milk-
23 based product. The packaging appears as:



42. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like E.P.

The Defendant Manufacturers' Inadequate Warnings

43. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

1 44. The Enfamil products Mead markets specifically for premature infants are commercially
2 available at retail locations and online. No prescription is necessary.

3 45. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the
4 significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with
5 Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide
6 instructions or guidance for how to avoid NEC.

7 46. Mead cites no medical literature or research to guide the use of its products.

8 47. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of
9 NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude
10 of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

11 48. Mead deceived the public, parents, physicians, other medical professionals, and medical staff
12 into believing that Enfamil products were a safe and necessary alternative, supplement and/or
13 substitute to breast milk.

14 49. Despite knowing that its products were being fed to premature infants, often without the
15 parents' informed consent, Mead failed to require or recommend that medical professionals inform
16 parents of the significant risk of NEC or to require that parental consent be obtained prior to the
17 products being fed to their babies.

18 50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents
19 believe that its products are safe and necessary for the growth of premature infants, despite the
20 products in fact being extremely dangerous for premature infants. Abbott's products significantly
21 increase the chances of a premature infant getting potentially fatal NEC.

22 51. The products Abbott markets specifically for premature infants are available at retail locations
23 and online. No prescription is necessary.

24 52. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk
25 of NEC (and resulting medical conditions, and/or death) associated with its products, or of the
26 magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to
27 avoid NEC.

28

53. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

NorthBay's Failure to Warn

55. On information and belief, NorthBay was aware of the significantly increased risk of NEC and death associated with providing Defendant Manufacturers' cow's milk-based products to its premature infant patients. NorthBay knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those dangers, or supplying breast milk-based feeding products to preterm infants like E.P., NorthBay has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

56. To that end, subsequent to E.P.'s NEC diagnosis, NorthBay staff published research titled "NEC-zero recommendations from scoping review of evidence to prevent and foster timely recognition of necrotizing enterocolitis" in "Maternal Health, Neonatology, and Perinatology." This research suggests NorthBay's longstanding awareness of the importance of "[p]rioritizing human milk" in NICU feeding protocols and makes clear that premature infants who are fed "donor human milk-based fortifier [have] reduced odds of NEC compared to those fed cow's milk based fortifier." Contrary to these recommendations and findings, on information and belief, from the time of E.P.'s diagnosis through present day, NorthBay has resisted the transition to an exclusive breast milk-based diet for preterm patients that would reduce NEC incidence and obviate the need to warn parents, like Margurite Pariani, of the risks posed by the Defendant Manufacturers' products.

57. NorthBay also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of necrotizing enterocolitis in

1 preterm infants by encouraging implementation of exclusive breast milk diets among new mothers.
2 Although NorthBay Medical Center currently maintains “Baby Friendly Hospital” designation status,
3 its embrace of the Initiative came too late for E.P.

4 58. Although NorthBay knew or should have known of the serious danger of the Defendant
5 Manufacturers’ products, NorthBay has continued to purchase, supply, and distribute these products
6 to preterm infants without providing full and adequate warnings of the attendant risks to parents,
7 healthcare professionals, and other medical staff at its relevant facilities. As a result, E.P. was fed the
8 Defendant Manufacturers’ cow’s milk-based products at NorthBay Medical Center, causing her
9 injuries. This occurred even though hospitals across the country, including NorthBay’s own hospitals,
10 warn and obtain consent from parents before providing other *safer* forms of nutrition, such as donor
11 breast milk.

12 59. NorthBay’s failure to warn of the risks posed by the Defendant Manufacturers’ products is
13 entrenched (and compounded) by the financial benefits it accrues from its relationships with the
14 Defendant Manufacturers. On information and belief, NorthBay has received the Defendant
15 Manufacturers’ cow’s milk-based products for free or at a significant discount, and has granted their
16 sales representatives access to NorthBay’s healthcare professionals and medical staff. These sales
17 representatives have provided deceptive information that NorthBay reasonably knew or should have
18 known would ultimately reach parents through those staff. This arrangement dovetails with the
19 Defendant Manufacturers’ own marketing strategy, which aims to “sell and service” healthcare
20 professionals and medical staff as a means of converting them into “extra salespersons.”

21 ***Safer Alternative Designs***

22 60. The Defendant Manufacturers’ cow’s milk-based products made specifically for premature
23 infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used
24 pasteurized breast milk instead of cow’s milk in their products, which would have produced a safer
25 product.

26 61. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically
27 designed for preterm infants, which contain no cow’s milk. This alternative design provides all the
28

1 necessary nutrition for growth and development that cow's milk-based products provide, without the
2 same unreasonably dangerous and deadly effects.

3 62. On information and belief, Abbott and Mead were aware of the significantly increased risk of
4 NEC and death associated with their cow's milk-based products, and instead of warning of the
5 dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the
6 foundation of their products.

7 **FIRST CAUSE OF ACTION**
8 **STRICT LIABILITY FOR DESIGN DEFECT**
9 **(Against Abbott and Mead)**

9 63. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

10 64. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation,
11 owed a duty to the consuming public in general, and Plaintiff in particular, to manufacture, sell, and
12 distribute their products in a manner that was not unreasonably dangerous.

13 65. Abbott and Mead also owed a duty to the consuming public in general, and Plaintiff in
14 particular, to manufacture, sell, and distribute their products in a manner that was merchantable and
15 reasonably suited for their intended use.

16 66. Abbott and Mead knew that their products would be used to feed premature infants like E.P.
17 and knew (or reasonably should have known) that use of their cow's milk-based products significantly
18 increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably
19 dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had
20 risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market
21 their defective products as appropriate for premature infants.

22 67. E.P. ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The
23 risks of feeding those products to E.P. outweighed the benefits. An ordinary consumer would not
24 expect those products to carry a significant risk of serious injury and death from NEC.

25 68. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition
26 did not carry the same risks of NEC, serious injury, and death that their products do.

27 69. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing
28 facility.

1 70. Abbott and Mead did not develop a human-milk based product that was safer for premature
2 infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death,
3 even though doing so was economically and technologically feasible and even though pasteurized
4 breast milk was an available alternative.

5 71. Abbott's and/or Mead's products were fed to E.P., which directly and proximately caused her
6 NEC and led to injury.

7 72. As a further direct result, Plaintiff Margurite Pariani has suffered significant emotional
8 distress, loss of income, and/or other harms. Her life has been significantly affected by E.P.'s injuries.

9 **SECOND CAUSE OF ACTION**
10 **STRICT LIABILITY FOR FAILURE TO WARN**
(Against Abbott and Mead)

11 73. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

12 74. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this
13 litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to provide
14 adequate warnings or instructions about the dangers and risks associated with the use of their products
15 with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and
16 death.

17 75. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and
18 sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing
19 their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the
20 unreasonable risk of harm posed by those ingredients, specifically including the significantly
21 increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in
22 this litigation unreasonably dangerous.

23 76. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the
24 infant products at issue in this litigation because they knew or should have known that their cow's
25 milk-based premature infant products would be fed to premature infants like E.P., and that their
26 products might cause E.P. to develop NEC, severe injury, or death, yet they failed to provide adequate
27 warnings of those risks. Among other risks, the Defendant Manufacturers:
28

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for E.P.; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like E.P.; and/or
- c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like Plaintiff Margurite Pariani; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

77. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

78. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, E.P. was fed cow's milk-based products, which caused her to develop NEC.

79. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants

1 cow's milk-based formula, they would not have fed E.P. those products. Had E.P.'s mother, Ms.
2 Pariani, known of the significant risks of feeding E.P. cow's milk-based formula, she would not have
3 allowed such products to be fed to E.P.

4 80. As a further direct result, Ms. Pariani suffered significant emotional distress, loss of income,
5 and/or other harms. Her life has been significantly affected by E.P.'s injuries.

6 **THIRD CAUSE OF ACTION**
7 **NEGLIGENCE**
8 **(Against Abbott and Mead)**

8 81. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

9 82. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation,
10 owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care
11 to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to
12 users, when such products are used in their intended manner and for their intended purpose.

13 83. At all times relevant to this action, E.P.'s healthcare professionals and medical staff used the
14 products at issue in their intended manner and for their intended purpose.

15 84. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created,
16 manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based
17 infant products at issue in this litigation and thereby breached their duty to the general public and
18 Plaintiff.

19 85. Specifically, although Abbott and Mead knew or reasonably should have known at the time
20 of production that their cow's milk-based infant products significantly increased the risk of NEC,
21 serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty
22 by:

- 23 a. Failing to warn that cow's milk-based products significantly increase the risk of NEC,
24 severe injury, and death for E.P.; and/or
- 25 b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for
26 premature infants like E.P.; and/or
- 27 c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and
28 provide a false sense of security in that they warn and instruct specifically on certain

1 conditions, but do not warn of the significantly increased risk of NEC and death;
2 and/or

3 d. Failing to insert a large and prominent “black box”-type warning that their cow’s milk-
4 based products are known to significantly increase the risk of NEC and death when
5 compared to breast milk in premature infants; and/or

6 e. Failing to provide well-researched and well-established studies that linked cow’s milk-
7 based products to NEC and death in premature infants; and/or

8 f. Failing to insert a warning or instruction to healthcare professionals and other medical
9 staff in the hospital that parents should be provided information necessary to make an
10 informed choice about whether to allow their babies to be fed the Defendant
11 Manufacturers’ products, notwithstanding their substantial risks; and/or

12 g. Failing to provide a warning in a method reasonably calculated/expected to reach the
13 parents of newborns, like Plaintiff Margurite Pariani; and/or

14 h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC
15 in premature infants associated with cow’s milk-based products.

16 86. In addition, although Abbott and Mead knew or reasonably should have known at the time of
17 production that their cow’s milk-based products significantly increased the risk of NEC, serious
18 injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing
19 to perform the necessary process of data collection, detection, assessment, monitoring, prevention,
20 and reporting or disclosure of adverse outcomes in infants who ingest their products.

21 87. As a direct and proximate result of the Defendant Manufacturers’ failure to act in a reasonably
22 prudent manner and their breach of duty, E.P. was fed cow’s milk-based products, which caused her
23 to develop NEC.

24 88. Had Abbott and Mead satisfied their duties to the consuming public in general, E.P. would
25 not have been exposed to their unreasonably dangerous cow’s milk-based products.

26 89. As a further direct result, E.P.’s mother, Ms. Pariani, suffered significant emotional distress,
27 loss of income, and/or other harms. Her life has been significantly affected by E.P.’s injuries.

FOURTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)

90. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

91. At all times relevant to this action, E.P. consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

92. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiff in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

93. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

94. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time E.P. was fed their products:

- a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or
- c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or

- 1 g. That their products were safe and more like breast milk than other infant products and
2 that they had removed the harmful ingredients of cow's milk when, in fact, the cow's
3 milk in their products was still capable of causing NEC, serious injury, and death;
4 and/or
5 h. That their products were based on up-to-date science, which made them safe for
6 premature infants; and/or
7 i. Omitting the material fact that their products significantly increased the risk of NEC
8 in premature infants.

9 95. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

10 96. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce
11 physicians and medical staff, including E.P.'s physicians and medical staff, to provide their infant
12 products to babies, including E.P.

13 97. Plaintiff Margurite Pariani was not aware that these misrepresentations were false and
14 justifiably relied on them. The Defendant Manufacturers' misrepresentations induced Ms. Pariani to
15 allow her child to be fed Abbott's and Mead's infant products, in reliance on all the messaging she
16 received about formula feeding, including, directly or indirectly, the Defendant Manufacturers'
17 messaging. Had Abbott and Mead not committed these intentional misrepresentations, E.P. would
18 not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based
19 products.

20 98. As a direct and proximate result, Abbott's and Mead's products were fed to E.P., causing her
21 NEC and subsequent injury.

22 99. As a further direct result, Ms. Pariani has suffered significant emotional distress, loss of
23 income, and/or other harms. Her life has been significantly affected by E.P.'s injuries.

24 **FIFTH CAUSE OF ACTION**
25 **NEGLIGENT MISREPRESENTATION**
 (Against Abbott and Mead)

26 100. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

27 101. At all times relevant to this action, E.P. consumed the products at issue in their intended
28 manner and for their intended purpose.

1 102. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation,
2 owed a duty to the consuming public in general, and Plaintiff in particular, to provide truthful,
3 accurate, and complete information about the risks and benefits of using their products when used in
4 the intended manner and for the intended purpose.

5 103. In the course of their business, Abbott and Mead breached their duty through
6 misrepresentations made to consumers, physicians, and medical staff in their advertising and
7 promotional materials, as described in previous paragraphs and incorporated herein, each of whom
8 were foreseeable recipients of this information.

9 104. Specifically, upon information and belief, Abbott and Mead made the following false
10 statements of material fact on an ongoing and repeated basis and prior to the time E.P. was fed their
11 products:

- 12 a. That their cow's milk-based products were safe and beneficial for premature infants
13 when they knew or should have known that their products were unreasonably
14 dangerous and cause NEC, serious injury, and death in premature infants; and/or
- 15 b. That their cow's milk-based products were necessary to the growth and nutrition of
16 premature infants, when they knew or should have known that their products were not
17 necessary to achieve adequate growth; and/or
- 18 c. That their products have no serious side effects, when they knew or should have known
19 the contrary to be true; and/or
- 20 d. That cow's milk-based products were safe for premature infants; and/or
- 21 e. That cow's milk-based products were necessary for optimum growth; and/or
- 22 f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- 23 g. That their products were safe and more like breast milk than other infant products and
24 that they had removed the harmful ingredients of cow's milk when, in fact, the cow's
25 milk in their products was still capable of causing NEC, serious injury, and death;
26 and/or
- 27 h. That their products were based on up-to-date science, which made them safe for
28 premature infants; and/or

- 1 i. Omitting the material fact that their products significantly increased the risk of NEC
2 in premature infants.

3 105. Abbott and Mead were negligent or careless in not determining those representations to be
4 false.

5 106. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce
6 physicians and medical staff, including E.P.'s physicians and medical staff, to provide their products
7 to babies, including E.P.

8 107. The Defendant Manufacturers' misrepresentations induced, and were intended to induce
9 Plaintiff Margurite Pariani, to allow her child to be fed Abbott's and Mead's infant products, in
10 justifiable reliance on all the messaging she received about formula feeding, including, directly or
11 indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these
12 negligent misrepresentations, E.P. would not have been exposed to their unreasonably dangerous
13 cow's milk-based products.

14 108. As a direct and proximate result, Abbott's and Mead's products were fed to E.P., causing her
15 NEC and subsequent injuries.

16 109. As a further direct result, Ms. Pariani suffered significant emotional distress, loss of income,
17 and/or other harms. Her life has been significantly affected by E.P.'s injuries.

18 **SIXTH CAUSE OF ACTION**
19 **NEGLIGENT FAILURE TO WARN**
(Against NorthBay)

20 110. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

21 111. NorthBay, as a purchaser, supplier, and/or distributor of the products at issue in this litigation,
22 owed a duty to the consuming public in general, and Plaintiff in particular, to purchase, supply, and
23 distribute products that were free of unreasonable risk of harm when used in their intended manner
24 and for their intended purpose.

25 112. At all times relevant to this action, E.P. used the cow's milk-based products purchased,
26 supplied, and/or distributed by NorthBay in their intended manner and for their intended purpose.

27 113. NorthBay employed or contracted with the healthcare professionals and medical staff at
28 NorthBay Medical Center, managing these individuals during their treatment of E.P.

1 114. NorthBay negligently supplied and distributed the Defendant Manufacturers' milk-based
2 infant feeding products to these healthcare professionals and medical staff for use on premature
3 infants, including E.P.

4 115. Moreover, at all relevant times, NorthBay knowingly authorized the Defendant
5 Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at
6 NorthBay Medical Center. The Defendant Manufacturers' sales representatives were encouraged to
7 interact with NorthBay's healthcare professionals and medical staff. These interactions provided the
8 Defendant Manufacturers' sales representatives an opportunity to co-opt NorthBay's healthcare
9 professionals and medical staff into assisting with the marketing, distribution, and/or sale of the
10 Defendant Manufacturers' unreasonably dangerous products to consumers, such as Plaintiff
11 Margurite Pariani.

12 116. NorthBay also knowingly allowed the Defendant Manufacturers' sales representatives to
13 routinely misrepresent the risks and benefits of their products to NorthBay's healthcare professionals
14 and medical staff, including the misrepresentation that premature babies would not grow adequately
15 with human milk and human milk products and that use of donor milk was not advised for premature
16 infants.

17 117. NorthBay knew or reasonably should have known at the time that it acquired, distributed, and
18 supplied the Defendant Manufacturers' cow's milk-based infant products that these products
19 significantly increased the risk of NEC, serious injury, and death.

20 118. Nonetheless, NorthBay failed to act in a reasonably prudent manner and breached its duty by:

- 21 a. Failing to warn that cow's milk-based products significantly increase the risk of NEC,
22 severe injury, and death in those babies; and/or
- 23 b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for
24 premature infants like E.P.; and/or
- 25 c. Failing to warn or instruct its healthcare professionals and medical staff on the
26 information that should be provided to parents in order to make an informed choice
27 about whether to allow their babies to be fed the Defendant Manufacturers' products,
28 notwithstanding their substantial risk; and/or

- d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to NorthBay's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

119. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

120. NorthBay knew or reasonably should have known that its medical professionals and the parents of premature infants, including Margurite Pariani, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

121. Had NorthBay exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, E.P. would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

122. As a direct and proximate result of NorthBay's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, E.P. was fed the Defendant Manufacturers' cow's milk-based products, which caused her to develop NEC and significant injuries.

123. As a further direct and proximate result of NorthBay's negligent failure to warn of the Defendant Manufacturers' unreasonably dangerous products, Ms. Pariani suffered significant

1 emotional distress, loss of income, and/or other harms. Her life has been significantly affected by
2 E.P.'s injuries.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Plaintiff prays for judgment as follows:

5 124. For compensatory damages in an amount to be proven at trial;

6 125. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain
7 and suffering, mental anguish, and other non-economic losses sustained as a result of Defendants'
8 conduct;

9 126. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost
10 profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental
11 health treatment which have or may be recommended;

12 127. For punitive damages resulting from Defendants' oppressive, fraudulent, and/or malicious
13 conduct, as permitted by law;

14 128. For interest as permitted by law;

15 129. For attorney's fees, expenses, and recoverable costs incurred in connection with this action;
16 and

17 130. For such other and further relief as the Court deems proper.

18 **DEMAND FOR JURY TRIAL**

19 131. Plaintiff hereby demands a jury trial for all claims triable.

20
21 Dated: March 23, 2022.

22 Respectfully submitted,

23 

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